



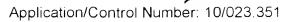


UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address AVAMISSS AVER FOR PATENTS POLICY OF THE AVAILABLE OF TH

APPLICATION NO	THEING DATE	URST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10 023,351	12 17 2001	Andrea M. Lever	P02452	2831
23702	7590 06 26 2003			
Bausch & Lomb Incorporated			EXAMINER	
One Bausch & Lomb Place Rochester, NY 14604-2701			AZPURU, CARLOS A	
			ART UNIT	PAPER NUMBER
			1615	$\overline{\zeta}$
			DATE MAILED 06 26 2003	,

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)				
		10/023,351	LEVER ET AL.				
	Office Action Summary	Examiner	Art Unit				
		Carlos A. Azpuru	1615				
	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
THE N - Exter after - If the - If NO - Failur - Any m	ORTENED STATUTORY PERIOD FOR REPLY MAILING DATE OF THIS COMMUNICATION, issues of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication period for reply specified above is less than thirty (30) days, a reply period for reply is specified above, the maximum statutory period we to reply within the set or extended period for reply will, by statute, eply received by the Office later than three months after the mailing dipatent term adjustment. See 37 CFR 1 704(b)	6(a) In no event, however, may a reply be turn within the statutory minimum of thirty (30) day; ill apply and will expire SIX (6) MONTHS trom cause the application to become ABANDONE!	nely filed s will be considered timely the mailing date of this communication D (35 U.S.C. § 133).				
1)	Responsive to communication(s) filed on	·					
2a) <u></u> □	This action is FINAL . 2b)⊠ This	s action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims							
4) 🖂	Claim(s) 1-16 is/are pending in the application.						
	4a) Of the above claim(s) is/are withdrawn from consideration.						
5)[Claim(s) <u>1-7 and 9-15</u> is/are allowed.						
6)⊠ Claim(s) <u>8 and 16</u> is/are rejected.							
7)	7) Claim(s) is/are objected to.						
	Claim(s) are subject to restriction and/or on Papers	election requirement.					
9) 🔲 🗆	he specification is objected to by the Examiner						
10) The drawing(s) filed on is/are a) accepted or b) objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner							
If approved, corrected drawings are required in reply to this Office action							
12) ☐ The oath or declaration is objected to by the Examiner.							
Priority u	nder 35 U.S.C. §§ 119 and 120						
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).							
a) All b) Some * c) None of:							
1. Certified copies of the priority documents have been received.							
	2. Certified copies of the priority documents have been received in Application No						
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 							
14)⊠ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).							
	☐ The translation of the foreign language provicknowledgment is made of a claim for domestic						
Attachment		- •					
2) Notice	of References Cited (PTO-892) of Draftsperson's Patent Drawing Review (PTO-948) lation Disclosure Statement(s) (PTO-1449) Paper No(s)	5) 🔲 Notice of Informal F	(PTO-413) Paper No(s) Patent Application (PTO-152)				



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DETAILED ACTION

Receipt is acknowledged of the information disclosure statement filed 01/16/03.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

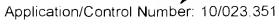
Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8 and 16 are indefinite in that they refer to a "sustained release form of the retinoid." Since the retinoid does not determine the release profile, but rather depends upon its formulation, it is suggested applicant amend the claims to particularly point out that the composition being claimed is in sustained release form. Correction is requested.



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Claims 1-7, and 9-15 are allowed. Amendment of claims 8 and 16 as indicated above would place all the claims in condition for allowance. Addition of an information disclosure statement containing the references listed at page 13 of the specification would place the application in condition for allowance.

Patents to Ushio et al and Park et al are cited as the closest prior art in their disclosure of administering vitamin A compounds to the eye. Neither is directed towards a method directed towards corneal epithelia, its integrity or health.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is 703/308-0237. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor. Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Application/Control Number: 10/023,351

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June 24, 2003

PRIMARY EXAMINER GROUP 1506